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EXAMINER	
STOUT, MICHAEL C	

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3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,265	BODECKER ET AL.	
	Examiner	Art Unit	
	MICHAEL C. STOUT	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,8-14,16 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,8-14,16 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 3-6, 8-14, 16 and 18 are currently pending. Claim 1 has been amended.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification discloses the device wherein the device is bended from a planar shape to an angled shape see Page 2, lines 6-13, but fails to provide antecedent basis for the language of "moves".

Moves has been interpreted to be directed towards the disclosure wherein the carrier is bended.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 3-6, 8-15, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brehmeier-Flick et al. (US 6083174) in view of Jeffries et al. (US 6193656) and B-Flick et al. "Study and Development of a Portable Telemetric Intracranial Pressure Measurement Unit." 19th International Conference Proceedings, IEEE/EMBS Oct. 30 – Nov. 2, 1997 Chicago, IL USA.

Regarding **claim 1** Brehmeier-Flick discloses an implant comprising a sensor device (sensor element 1,see Column 4, Line 19) being fixedly connected to a first end of a longitudinal carrier (flexible foil 3, see Column 4, Line 20 and Figure 1); and an inductive coil (telemetry unit 2, see Column 4, Line 22) connected to the sensor device via electrical connection lines (strip conductors 4, see Column 4, Line 20) that are arranged on the longitudinal carrier; a covering encapsulating the sensor device (layer 6b, See Column 4, Line 39), the carrier with the connection lines (layer 6a, See Column 4, Line 37), and the coil (6c, See Column 4, Line 39) ; wherein the carrier has a sufficient rigidity such that the sensor device is adapted to be guided by the carrier during implantation to a target position and held in position at the target position (the flexible foil 3 is easy to implant because it can be slid under the skin without twisting or being moved in a undesirable direction, see Column 4, Lines 24-27, Figure 2 shows the flexible foil 3 which a sensor and telemetery unit 2 arranged thereon along with strip conducts, the sensor and telemetry unit each have a protective layer of 6b and 6c respectively, Figure 2 which is a cross -section view of the implant in Figure 1 shows the foil having a rectangular cross section see Figure 2, and furthermore Figures 1 and 2 combined show a foil 3 comprising a rectangular cross section along the shortest with dimension shown in Figure 1).

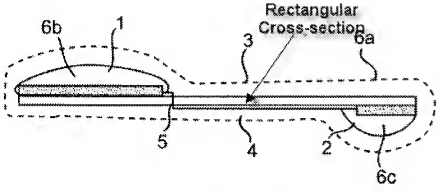

FIG. 2

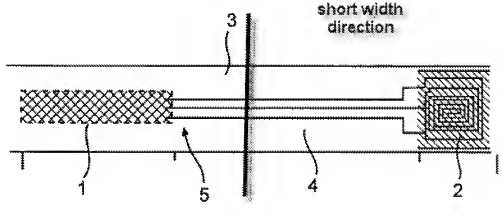

FIG. 1

Brehmeier-Flick teaches the device wherein the carrier is formed of a thin flexible film which is rod-shaped with a rectangular cross-section, see Figures 1 and 2 above, wherein the carrier is substantially planer shape (Figures 1 and 2) and is bendable from said planar shape to a shape wherein the carrier is arranged at an angle relative to the

plan in which the coil windings of the inductive coil are arranged (the film is flexbile and capable of bending such that the carrier is arranged at an angle to the coils 2). While

Brehmeier-Flick fails to explicitly state the carrier moves from a planar shape to a shape wherein the carrier is arranged at an angle of 60 to 120 degrees. The claim limitations are drawn structure implied by the process of using the device to permit the device to bend from a planar shape to an angle from 60-120 degrees. One of ordinary skill in the art at the time of the invention would recognize that the flexible film taught by Brehmeier-Flick is an equivalent structure (a thin film having flexibility) which can be bended from a flat shape to an angle, see page 2 of the applicant's specification.

The Applicant's specification discloses the structure which implied by the process of the carrier moving (bended) from a planar shape to an angle., "The carrier may for example be formed as thin polyimide foil which for stiffening may comprise a cambered form. The carrier may also be rod-shaped with a rectangular cross-section or a circle segment cross-section."

As mentioned above Brehmeier-Flick teaches a rod-shaped foil with a rectangular cross section. Brehmeier-Flick fails to teach the carrier material.

B-Flick teaches the carrier material is polimide tape, See Page 978, Paragraphs 1-3.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the device taught by Brehmeier-Flick to include a poyimide carrier as taught by B-Flick in order to provide a biocompatible substrate for mounting the sensor and coil component. The device taught by Brehmeier-Flick in view

of B-Flick teaches equivalent structure to the applicant's disclosed invention which can be used in the process wherein the foil moves from a planar shape to an angled shape.

Brehmeier-Flick fails to disclose a device wherein the covering part has means for subcutaneous fastening. Jeffries teaches an implant comprising a covering part (housing 500, see Figures 5-8) having a means for subcutaneous fastening (eyelets 502 and 504, see Figure 5).

Both Brehmeier-Flick and Jeffries teach implant devices. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device disclosed by Brehmeier-Flick to include have a means for subcutaneous fastening as taught by Jeffries in order to connect the sensor to a site in the body, see Jeffries Column 2, Lines 25-33.

Regarding **claim 3,** Brehmeier-Flick further discloses a device wherein there are provided two connection lines between the coil and the sensor device (see Figure 1).

Regarding **claim 4,** Brehmeier-Flick further discloses a device wherein the carrier is flat (see Figure 2).

Regarding **claims 5-6,** Brehmeier-Flick further teaches a device further comprising a stiffening foil being provided in the covering part (the flexible foil while being the carrier also provides stiffening for successful implantation, see Column 4, Lines 24-27) and the carrier is formed as a foil (flexible foil 3) .

Regarding **claim 8 and 9,** Brehmeier-Flick further discloses a device wherein a frame formed in one piece with the carrier (area of the carrier immediately surrounding the sensor, see Figure 1) is fastened at the first end of the carrier, the sensor device

positively fits within the frame (the sensor device fits within the frame area of the carrier, see Figure 1).

Regarding **claim 10,** Brehmeier-Flick further discloses a device wherein the carrier is formed as a common carrier (all of the components are arranged on the flexible foil 3, see Column 4 Lines 19-21 and Figure 2) for the electrical connection lines and the coil windings.

Regarding **claim 11,** Brehmeier-Flick further discloses a device wherein the sensor device comprises at least one pressure sensor (see Column 4, Lines 7-18).

Regarding **claims 12, 13, 14,** Brehmeier-Flick further discloses a device wherein the covering part encapsulating the coil is adapted to be arranged in an interior of the brain, (the covering part 6a is made of silicone, a pressure transmitting medium, Column 4 Lines 32-39) and is equipped with a pressure capable of providing at least one of an intraparenchymal and intraventricular pressure measurements once positioned in an interior of the brain, see also Column 1, Lines 39-56.

Regarding **claim 15,** see claim 1 above.

Regarding **claim 16** Brehmeier-Flick further discloses a device wherein the covering part encapsulating the coil is adapted to be arranged in the epidural (the covering part 6a is made of silicone, a biocompatible material, see Column 4, Lines 32-39 and Column 1, Lines 39-56).

Regarding **claim 18** Brehmeier-Flick/B-Flick teaches the implant of claim 13, wherein the carrier is bendable substantially about a line adjacent to said inductive coil (Brehmeier-Flick/B-Flick teaches a rectangular flexible foil formed from polyimide and

having a rectangular cross section which is capable of being bent adjacent to the inductive coils).

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-6, 8-16 and 18 have been considered but are moot in view of the new ground(s) of rejection.

The Amendments to the claims present the newly amended claim language of wherein the carrier "moves from said planar shape to a shape wherein...," wherien previously the carrier was "*bendable* from....".

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., *structure*, which is discloses on page 4, lines 29-30 and in Figure 1) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The Applicant's arguments are directed towards structure disclosed by not claimed. The current claims are directed towards *structure implied* by a process of using the device wherein the carrier moves (is bended) from a planar shape to an angled shape.

The applicant further goes on to argue that the implied structure is not taught or suggested by Brehmeier-Flick or B-Flick. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

As set forth in the above rejection Brehmeier-Flick in view of B-Flickt teaches an equivalent structure configured to performed the process of using the device as claimed wherein the substrate moves from a planar to angled position.

The applicant's further arguments are directed towards the method of use/application of the device disclosed. The claims are drawn to an apparatus and patentability is determined based on the structural differences of the instant application and the prior art.

Contact Info

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL C. STOUT whose telephone number is (571)270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. C. S./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736